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| IN THE MATTER OF THE | § | BEFORE THE |
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| COMPLAINT AGAINST | § | TEXAS STATE BOARD |
| | § | |
| STANISLAW R. BURZYNSKI, M.D. | § | OF MEDICAL EXAMINERS |

BEFORE EARL A. CORBITT, ADMINISTRATIVE LAW JUDGE

VOLUME I OF II

MAY 24, 1993

DUPLICATE

HELEN M. WILDE
Certified Shorthand Reporter * SB 0028486 *
3604 Laurel Ledge Lane
Austin, Texas 78731 452-6613

Institute, et al, found at 819 F.2d, Page 1301, Fifth Circuit 1987, found under Tab 19 of the notebook.

JUDGE CORBITT: Mr. Jaffe, you stated before that you had no objection to these exhibits?

MR. JAFFE: That's correct. No objection to any of them.

JUDGE CORBITT: The exhibits stated by the staff are admitted.

(Exhibits Numbers 14 through 26 (were received into evidence.

MR. HELMCAMP: At this time, Judge, the staff would rest as to its case in chief.

JUDGE CORBITT: Mr. Jaffe, you may proceed, sir.

MR. JAFFE: Thank you. Respondent would call Dr. Nicholas Patronas.

JUDGE CORBITT: And the last name?

MR. JAFFE: Patronas.

JUDGE CORBITT: Doctor, why don't you have a seat up here, please. Would you raise your right hand, please?

NICHOLAS PATRONAS, M.D.,

called as a witness by the Respondent, after having been first duly sworn by the Judge to tell the truth, the whole truth, and nothing but the truth, testified as follows:

JUDGE CORBITT: Thank you very much. Would you state your name and spell your last name for our court reporter?

DR. PATRONAS: Nicholas Patronas, P-a-t-r-o-n-a-s.

THE REPORTER: And the Nicholas, please, how do you spell the Nicholas?

DR. PATRONAS: N-i-c-h-o-l-a-s.

THE REPORTER: Thank you.

JUDGE CORBITT: You may proceed.

DIRECT EXAMINATION

BY MR. JAFFE:

Q Dr. Patronas, what is your profession?

A I'm a radiologist, a medical doctor specializing in radiology.

Q Would you tell us briefly your educational background?

A Well, after the medical school we have a year internship, four years residency in radiology, and in addition, I had an extra year of training in neuroradiology. So my subspecialty is neuroradiology. It is the evaluation of the regions of the central nervous system.

MR. JAFFE: One moment, Your Honor.

BY MR. JAFFE:

Q And would you relate your work experience, please?

A When I finished my training I was at the University of Chicago for seven years as a staff radiologist at the University Hospital. And then I moved to the National Institutes of Health where I worked from '81 to '85 as a staff radiologist at the clinical center, which is the hospital of the National Institutes of Health. Then I moved to Georgetown University where I became full professor of radiology. And the National Institutes of Health contracted Georgetown radiological services, and I was sent from Georgetown back to NIH to cover the section of neuroradiology, where I'm currently a Chief of the Section of Neuroradiology.

Q And so you work at the National Institutes of Health hospital; is that where you work?

A Yeah, at the hospital initially as a federal employee from '81 to '85, and then on contract from Georgetown University. So I am one of the 17 radiologists who provide radiological services to the National Institutes of Health, to the hospital of the National Institutes of Health.

Q What is the function or purpose of the hospital of the National Institutes of Health?

A As you know, there are a lot of research protocols that

are going on, and people who are admitted to this facility are being admitted to try experimental treatment. As they are admitted to the hospital, the hospital requires an X-ray Department and radiologists to man the department. And so we evaluate the various lesions that are being admitted under these approved protocols, and we assess the effectiveness of the treatments given there, using imaging modalities such as MRI or CT scans and regular radiology.

Q And that would be for the various health departments or what's called institutes?

A Exactly, the various institutes, yes.

Q Like the National Cancer Institute, that's one of them?

A That's the biggest of all, yeah.

Q What-- Basically then, you do the, just in layman's terms, you do all the imaging work and interpretation for the National Cancer Institute testing of drugs?

A Exactly.

Q Because-- and what happens is, they give the drugs to the people and you have to get-- they have to have a scan before to see what they had--

A Exactly.

Q --then when they go into treatment they have to get scans to see what, if any, effect--

A To see whether they are effective or not, yes.

Q And that's--

A That's my job, to assess the effectiveness of the drugs that are given there and to provide the diagnosis at the initial stage, upon admission.

Q Dr. Patronas, did there come a time when you became aware of Dr. Burzynski?

A Yes, it was when Michael Hawkins from NCI asked me to join a group of other physicians and scientists and come to Houston on a site visit to Dr. Burzynski's Institute in order to assess the best case scenarios that he had to present us of his patients who were treated with antineoplastons. So that was the first time when I was aware that there is an anticancer agent. And I was called as an expert in assessing the images to evaluate, together with the rest, the other five members of that team, to evaluate the effectiveness of his treatment.

Q And did you have occasion to actually go down to Houston, Texas?

A Yes, we spent about seven hours at the Burzynski Institute and we reviewed the material that was given to us.

Q What material did you review?

A Initially there was a presentation of the cases by Dr. Burzynski; each individual case was studied separately. We were given the history, the pathology, the previous treatment and the timing of these treatments, and we have somebody who recorded these data.

Then the histological slides were presented to one of our neuropathologists, one neuropathologist who was also a guest consultant in the team. He reviewed the slides and confirmed the histological grade of the tumor that Dr. Burzynski was indicating in his presentation.

Then there was assessment of the images, either CT scans or CAT scans, or MRI scans. They were serial studies in any given patient. So we were able to see how the tumor started and how it ended up under treatment.

Q How many patients did you concern yourself with at that time?

A We reviewed the material of seven cases. We did not have more time to review more. These were the--

Q So that basically took up the whole day?

A The whole day, yes; approximately one hour per case.

Q And what happened after you reviewed the cases?

A Well, we took our notes and we discussed the findings, and there was a report that was issued indicating what we had found.

MR. JAFFE: May I approach the witness, please?

JUDGE CORBITT: Yes, sir.

MR. JAFFE: Let me mark for identification Exhibit Number 27, I believe we are up to, Judge?

JUDGE CORBITT: Number 27 will be next.

BY MR. JAFFE:

Q We have marked for identification Exhibit 27. Will you see if you can identify that for us?

A Yeah, I have seen this, yeah.

Q And is this-- What exactly is this?

A It was a letter to Dr. Burzynski from Dorothy Macfarlane, one of the people who was part of the team. And the memorandum shows or summarizes our findings for each individual patient. And this is exactly the document that we came up with.

Q What was the basic conclusion of the-- that you indicated?

A The basic conclusion was that in five of the patients with brain tumors that were fairly large, the tumor resolved, disappeared.

Q Was that just happenstance? I mean, was that just by some miracle of--

A Well, since the treatment that was given started after the previous conventional treatments which had failed previously, we took the position that this probably represents the result of this new treatment. And so there was only minimal residual tissue at the tumor bed, which looked like a scar, and had no fissures to suggest that there was a tumor in the majority of the cases.

Two of the seven patients did not do very well. One of them deceased. The tumor dissolved at least

microscopically; we could see it with the naked eye, but it recurred later, a year later. And the other, there was very, very minimal decrease in the size of the tumor. But the tumor was very big, the last one, the seventh. So the last two cases did not survive, although there was definite improvement in one of the two last cases.

Q I guess that would be called an objective response in that these patients--

A Exactly, because we were six people and we all looked at the images and we saw the chronological order. We checked the names of the patients on the films, and the films were obtained at different institutions from the entire country, basically where the patients were located. And we had no reason to believe that these were not the results of the treatments.

Q Doctor, based on what you have testified to before about your background and credentials, it's fair to say, isn't it, that you have seen a lot of brain cancer patients?

A Yes, in fact, we see a lot of these cases.

Q And that's part of what you do at the hospital, is to evaluate treatments on brain cancer patients?

A Well, different cancers, but since I am the neuroradiologist I see all brain tumors. And I see a large volume of them.

Q Now, with regard to at least the five patients, I think

you testified that five of the patients had their tumors resolved, they all--

A Disappeared.

Q --disappeared. Can you give us some kind of context of that? How often does that happen with any-- with no treatment, just by spontaneous remission, or by whatever it is that you--

A I'm not aware that spontaneous remission occurs; I don't think it does. And the available treatments only rarely produce results like that. The only medication-- the only treatment, which I think is the last resort, is radiation therapy. Chemotherapy has very little to offer unless there is an experimental protocol somewhere. However, conventional chemotherapy is-- provides very little, nothing, basically.

Radiation, there are some reports indicating that radiation treatment in children particularly could lead to resolution of the tumors, although I don't know whether it is a permanent one or temporary. So when this happens it is very rare, and I have seen only isolated reports here and there where that has happened with radiation.

Q With one case here or there--

A Yeah.

Q --an isolated report, you are talking about on a case by

case basis?

A Yeah. Well, radiation should give these results, if it works at all, the first two months after completion of the treatment. In these cases, all the patients had already failed radiation because they were treated months, several months after radiation was given and had failed.

Q What happens with these patients? Let's say they failed radiation; what happens then to the patient with brain cancer?

A Well, it depends on the grade of the tumor. If the tumor is low grade, astrocytoma, and we are talking about primary gliomas, if it is low grade, survival for years is possible. If it is an intermediate grade, the anaplastic, the mean survival is two years, and if it is the high grade glioma the mean survival is about 12 months. That's it; they die in 12 months, they disappear.

Q Now-- So are you saying basically that for someone that's failed radiation-- It sounds like you are saying that if someone has already failed radiation, at least, that there's not too much else--

A Nothing to offer, exactly.

Q --and that those people are going to eventually die of their disease, barring any unforeseen event or cure?

A Exactly.

Q And there is nothing that any-- that you could do at NCI?

A Nothing we can do, no; not at the present time.
Q All right. What about these five patients that are all basically doing-- how come they lived?
A Well, it's amazing, the fact that they are living and some of them are doing well. They are not-- they are not handicapped from the side effects of any treatment, and side effects of the most aggressive previous treatment are worse than the tumor itself. So these particular individuals not only survived, but they didn't have major side effects. So I think it is impressive and unbelievable.
Q How many times have you ever seen this, in your experience, that someone comes with a drug like this, to have this kind of effect? How often does that happen?
A I don't-- I have not seen it at any time with the medication that is given systematically. We have done-- we have an experimental protocol at the NIH where we inject a chemotherapeutic agent through the carotid artery, the artery that goes to the brain, and we have three survivals with this technique, by providing massive amounts of chemotherapeutic drugs to the brain that harbors the tumor.

And we destroy the tumor, but we destroy a large part of the brain as well, and the patients became severely handicapped, and a life that's not worth living.

And so I have three cases with this particular experimental protocol which resulted in killing the tumor, but a large part of the healthy brain as well.

So overall, the protocol was abandoned and is not any more in effect because of the serious side effects that we witnessed.

Q Now, let me ask your opinion or advice. Based on what you have seen from these patients-- I mean, I think the opinion actually, or the letter actually concludes that the site team concluded that there was antitumor effect from the antineoplastons.

What would happen, let's say for some reason Dr. Burzynski's brain tumor patients can't get the medicine any more and have to go off treatment. What's going to happen to them, in your opinion?

MR. HELMCAMP: Objection, Your Honor, not relevant.

MR. JAFFE: I think it's relevant; I think it's relevant at least to the level of the facts-- The issue in this case is going to be what, assuming a violation has occurred, what's going to happen to Dr. Burzynski in terms of his ability to practice medicine. And certainly, based on the prior rulings of Your Honor and Mr. Martin, that's really the issue we are advocating in this case.

JUDGE CORBITT: I'll overrule the objection.

You may answer.

THE WITNESS: I think these patients will die.

MR. JAFFE: One moment.

BY MR. JAFFE:

Q One of the patients you reviewed was P.M.; is that correct? What happened in his case?

A The tumor was very large and involved the hypothalamus, a very sensitive part of the brain that cannot be operated, and had both cystic components and fleshy components, mass like. And the lesion disappeared. This patient did not have previous treatment, if I recall, other than-- previous chemotherapy or radiation, and the tumor disappeared under our eyes.

It was a low grade astrocytoma, which is compatible with long survival. However, even those low grade astrocytomas, when we see them, they don't go away even though they may permit the person to live for many years. In this particular patient's case the tumor disappeared, and there was a small, tiny remnant left, small percentage of the original size. And there has been several years since then and the patient is well, I'm told.

Q So at least for that patient you would not recommend that

he go off the treatment, would you?

A No.

MR. JAFFE: No further questions.

JUDGE CORBITT: Mr. Helmcamp, any Cross?

CROSS-EXAMINATION

BY MR. HELMCAMP:

Q Dr. Patronas, I'm not quite sure of the status of the-- the National Institutes of Health, is that a part of the federal government--

A Yes.

Q --or is that a private organization?

A No, it's the National Institutes of Health, it's national--

Q And-- I'm sorry I didn't mean to--

A It's a federal institution.

Q Thank you. And do I understand that you perform services for the National Institutes of Health pursuant to a contract with Georgetown University?

A At that time I was with Georgetown. That is a contract that is renewable every five years, and they bid-- bid, the different institutions at the end of completion. And whoever gets the next contract is our next boss. Right now we are under the Jackson Foundation. The-- Georgetown

lost the contract, so I'm employed by the Jackson Foundation. But still I work in the same premises as I have been since '81, under the same capacity.

Q I see, okay. Thank you.

The seven cases that were presented to you by Dr. Burzynski, are you aware whether or not these, quote, best case submissions were or were not being treated with any other form of chemotherapy or drugs, other than antineoplastons?

A I believe there-- from what the history, the charts themselves were not reviewed by us; Dr. Burzynski summarized, and he consulted every time, he read from the charts exactly what these patients were receiving. And to my recollection, none of them were receiving anything else except I believe one, Vincristine, I believe one patient of the seven.

But basically they had completed their conventional chemotherapy. They had completed the radiation therapy except for one who didn't have that, and the rest had-- and then they had nothing else to do. And so they went to Dr. Burzynski because the results of the conventional treatments were not there.

Q Thank you. Now, did I understand your answer, and I think I did, but I want to be clear on this. What you looked at was again, in layman's terms, X-rays of these various

seven patients? You saw those physically yourself?

A Exactly.

Q All right, and you saw, I presume, X-rays that had been taken at some time in the past and then another X-ray of that same patient after the treatment with Dr. Burzynski's antineoplaston?

A Exactly.

Q All right. Forgive me for asking this, but I must. How can you determine that you were looking at exactly the same X-rays?

A Exactly the same patient, you mean, the same patient's X-rays?

Q Yes.

A Each image has printed the name of the patient, and these X-rays were obtained in different institutes, in different facilities, so they were not locally obtained at Houston. Some of them were obtained-- but they were serial X-rays. Some of the X-rays were obtained in various labs at the location, the hometown of the patients.

Q Were any of these laboratories outside of the State of Texas, or were they all in the State of Texas?

A No, there were several outside the State of Texas.

Q Now, what effect might it have on your opinion if you knew that the patients had been treated with something other than the antineoplastons of Dr. Burzynski? And I

think in your study you described AS-10 or A10 and AS2-1?

A Uh-huh.

Q What if they had received something else; would that affect your decision or your conclusions about the shrinkage of the tumors?

A I would be surprised if anything else has caused that because I don't know of any active agent that produces these results. And if there was one I would like to know its name, for my own education.

Q I'm also interested-- You said, Doctor, you did not examine the charts of the patients themselves?

A They were on the top of the table in the conference room where Dr. Burzynski was leafing through and was telling-- reading to us from the charts what were the pertinent data and the questions that we were asking. The time allocated to us, I mean, the time we had was not sufficient to go over every single page of the charts. So that's how we gather the data, the clinical data.

We had-- the raw data were the slides, the actual histological slides, and the X-rays, which were the most important for us to see.

Q Now, one of the patients, at least one of them in fact, died during this process. I believe it was in April of 1990; is that correct?

A I think two died; one seven months later and the other a

year and five months later. I don't recall the exact timing. The one who died a short period after the treatment, which by the way only lasted a month or two, I believe, was not a long treatment. She had a huge tumor covering a large part of the brain. And this is the person who did not live long, many months; it was only, I believe, seven months.

Q What is Methotrexate, M-e-t-h-o-t-r-e-x-a-t-e?

A It's a chemotherapeutic agent given to cancer patients.

Q And I see here on Patient Number 4, a seven-year-old white male, that this individual took the A10 capsules, the AS2-1 IV and also a low dose Methotrexate?

A Uh-huh.

Q So he had at least one patient that was taking--

A I think there is another who took Vincristine also. There was, for a short period of time, and this drug given in combination with other drugs, and also a higher dose of all of them has provided zero results to this type of tumors.

Q When you say has provided zero results--

A Well, no survivals.

Q So for those, and I think there are at least two patients that you have described, I think Patient Number 4 and Patient Number 5, that were also on what we might call accepted or approved chemotherapy medications--

A Uh-huh.
Q --at the same time they were taking the antineoplastons?
A For a short period, I believe; not during the entire period of the antineoplaston treatment.
Q And that's based on what Dr. Burzynski told you?
A This is exactly what he told us, yes.
Q All right, sir. And so, of course, if there was something else that might be in the charts, obviously because you didn't have the time to review them, you wouldn't be aware of that?
A I would not.
Q I see. Can you state with any scientific certainty that the antineoplastons affected the tumors, or whether it might have been due to some other factors that we don't know?
A Well, we don't have an explanation for it, and so we have attributed, since these people had already the conventional treatment and they received nothing else, as we were told, we had presumed that what made the tumor shrink was the treatment that these patients received at the Burzynski Institute.
Q Now, in your work with the National Cancer Institute, are you aware of how one acquires Food and Drug Administration approval to treat patients?
A No, I don't know this, I have not-- I'm not on the

clinical end of the medical spectrum; I'm on the diagnostic end. And I'm not treating patients; therefore, I have not been through this process myself. I could not say much about it.

Q And forgive my questions if they seem somewhat redundant here, but I'm just trying to kind of get some information out.

Are you aware, or have you ever participated in clinical trials of an IND, an Investigational New Drug Application? You see, I thought that's what you do.

A No, no. The clinicians do this; this is their homework. They have to go through these various steps, and finally, through their committees and through the Institutes, they have a pyramid or a pyramidal system. They go through all the various steps, and finally a protocol is approved. And once it is approved patients start coming in. And we are to evaluate the diagnostic element of their disease. And this is where I enter the picture. I have no solid knowledge of the various steps that are--

Q I understand, and that's what I thought was your role, is sort of that, you know, to evaluate after the protocol has been established, et cetera, et cetera, and then try to determine through your specialty whether there is any measurable or objective changes in the different things.

A Exactly, that's where I--

Q So you do have some general familiarity, at least, that there is a requirement that one goes through before you can treat patients with drugs?
A Definitely, yes; definitely.
Q Is that important to do that?
A Well, it is the law. It is important, I guess, because otherwise nobody would-- I mean, this is what is our routine. So at the National Institutes of Health this is how it's done.
Q And you started to say, I think, that if it wasn't the law, then nobody would ever submit their drugs through this rigorous testing process, would they?
A Well, in the National Institutes of Health, I know that they have to go through various steps. And these steps are mandatory. And they would not be approved by the Chief of the Institute or the committee that assesses the merits of a given protocol to go ahead. So there are many ideas that are floating around, but several come to actually be tried, yeah.
Q And the ultimate fruition being, you know, the approval by the Food and Drug Administration, and thus a drug being readily marketable, accepted for--
A I don't know the other steps. I have no idea how it is done after that.
Q Again, this may be beyond the areas or your expertise, and

if so, I understand. But it would seem to me that one of the reasons we require and it is the law, as you have said, that a protocol be established, is to provide that scientific river to make sure that when we get a new drug, regardless of what it's supposed to do or what it's supposed to treat, that it is in fact going to do that; is that correct?

A Yeah. This is why we do that.

Q And in fact to make sure that the drug is safe and effective for that purpose for which it will be approved; is that not also correct?

A Yeah.

Q Now, are you aware that Dr. Burzynski has been treating patients in Houston, Texas, oh, since about 1977?

A I came to realize that this is the case after my site visit.

Q Are you aware also that at the present time Dr. Burzynski has an IND-approved-- approval for AS-10 testing in advanced breast cancer patients?

A I don't know.

Q Are you aware of any other INDs that Dr. Burzynski may have at the present time?

A No, not firsthand.

Q Would it surprise you to learn that since 1989 Dr. Burzynski has been free by the FDA to pursue his IND, the

clinical testing required to get the full marketing and approval of the drug?

MR. JAFFE: Objection. First of all, the witness already testified that he's not aware of this IND.

Second of all, the question is improperly formed insofar as it's not the case-- it assumes a fact which is exactly not the case, that once he gets this IND performed he can-- it gets to be approved for clinical tests-- for interstate marketing, which is just not the case.

This witness has already testified that he doesn't really know anything about the drug.

THE WITNESS: Exactly, I said that.

MR. JAFFE: Let me--

THE WITNESS: Sorry.

MR. JAFFE: And I think I exercised a great deal of discretion here. This man is a neuroradiologist. He's already testified he doesn't know very much at all about the drug approval process. But when you start getting into facts which are not the case under federal law, that's where I have to interject.

So I would like at least a more specific question, especially one that's not based on information which he said he doesn't have.

JUDGE CORBITT: Mr. Helmcamp, any response?

MR. HELMCAMP: I think I'll try to rephrase the question and see if I can do a little bit better, Your Honor.

JUDGE CORBITT: Have at it.

BY MR. HELMCAMP:

Q In your experience, if you can state, how long after an IND is approved does this testing process normally take, if you have any experience?

A I have none.

Q You have no experience in that regard?

A No.

Q Okay. Do you have an opinion as to whether or not FDA approval should be required before a physician is entitled or allowed to treat patients on a very large scale with a new drug?

A I don't know the regulations. I do not know the regulations on this topic.

Q I understand that you don't--

MR. JAFFE: I think I will object to that. The witness has already testified that he doesn't really know anything about FDA approval. We don't know-- We are really now talking about state law, because again, the question assumes something that's not a fact, that the

federal government, of which this individual is an employee, has something to do with the regulation of the practice of medicine, which under federal law it does not, and there are cases to that effect. The federal government doesn't have anything to do with the regulation of the practice of medicine, and we are being asked an opinion from this witness, who is a federal employee as a neuroradiologist, whether that should be the case. So I don't believe that anything that this witness has said heretofore establishes a predicate or foundation for him to even answer that question.

JUDGE CORBITT: The witness said he did not have an answer to your question, so--

MR. JAFFE: Never mind.

MR. HELMCAMP: I think he--

JUDGE CORBITT: It was a nice objection, but that's a requirement.

Go ahead.

BY MR. HELMCAMP:

Q I believe your answer was you are not familiar with the law. I'm just seeking your opinion. As a physician, which you are, do you believe that it is important, or is it your opinion that doctors should not be allowed to treat patients with drugs that have not been approved by

the FDA?

A I believe that doctors must follow the law, like every other citizen. And this is what I believe, and I think I am doing this myself.

MR. HELMCAMP: Pass the witness.

JUDGE CORBITT: Any Redirect, Mr. Jaffe?

MR. JAFFE: Just one or two questions here.

REDIRECT EXAMINATION

BY MR. JAFFE:

Q Dr. Patronas, let's assume that one of these seven patients had Methotrexate for a short period of time, or even a long period of time. Let's assume another had Vincristine. Has Methotrexate ever been shown to be effective in brain cancer?

A Not that I know of. In this dose and in a short period of time, even with combination with other medications, I don't think Methotrexate has done the expected-- the results that we wanted to see, no.

Q And indeed, it is the case that there are some chemotherapeutic agents now being used in the treatment of brain cancer. BCNU, would that be one?

A Yes, there is a rationale and there are some statistical data indicating that these chemotherapeutic agents prolong

the life of the patient. But if you look carefully at the prolongation of life, it's two or three months on the top of what was expected. So it's really not meaningful prolongation. But for some people it's important. So it is performed as long as the patient is willing to take these medications.

Q Are there side effects to BCNU?

A Well, basically the bone marrow is suppressed and the white cells and red cells and the platelets of the blood are decreased, and patients suffer infections and they have a number of complications as a result of it. So there are a lot of complications, and the gain is marginal. But it has been documented that there are marginal gains. That's why people are being treated today with these drugs, for these marginal gains.

Q Now, are the gains that you have documented, or the information you have documented in these five to seven cases, are they what you would call marginal gains?

A No, no, definitely not. When I say marginal gains, meaning a sense of survival. The tumor does not go away with these medications, with Methotrexate and the conventional. It just slows down the growth and so the patient is allowed to live a few extra months.

What we see here with antineoplastons, it was near complete resolution of the tumor and long survival,

not marginal survival. So we have a different picture here.

Q Now, let me just-- just to finalize this point, basically what I'm-- Basically what you are saying is that at least from what you've seen in your 20 years of experience, the treatment that you have been evaluating, even the experimental treatments with the BCNU, has anything ever come close, any of these chemotherapeutic agents ever come close to what you have seen in these seven cases?

A As I said, only radiation treatment has shown some results. These are well known and published. And these chemotherapeutic agents have not brought results close to what I saw without massive complications.

MR. JAFFE: No further questions.

MR. HELMCAMP: Just a few more on Recross.

RECROSS-EXAMINATION

BY MR. HELMCAMP:

Q I note there is an attachment as part of Exhibit 27 that's-- I'm going to style it kind of a press release. It's the last two pages of the exhibit, Doctor, if you would turn with me to that. This is from the National Cancer Institute; is that correct?

A This is from the National Cancer Institute, yes.

Q And if you turn with me to page-- Well, first, let's start with Page 1. This press release, if I may style it that, it looks like it's from The Cancer Information-- I'm sorry, strike that.

It says, "To determine whether the antitumor activity was due to treatment with antineoplastons..." and I'm reading from the middle of the second paragraph on Page 1. It continues, "...NCI..."

JUDGE CORBITT: Mr. Helmcamp--

MR. HELMCAMP: Yes, sir?

JUDGE CORBITT: --let's let the doctor find where you are reading.

THE WITNESS: Where are you reading, sir?

JUDGE CORBITT: The last couple of pages.

MR. HELMCAMP: I apologize, Your Honor. I didn't mean to--

THE WITNESS: Yeah, okay.

BY MR. HELMCAMP:

Q This document right there, that's the one I'm on (indicating).

A I see, okay. Yeah?

Q The second full sentence in the second paragraph of that document I believe you now have in your hand says, "To

determine whether the antitumor activity was due to treatment with antineoplastons, NCI plans to conduct four phase II trials using antineoplastons in patients with a brain tumor."

Have you done that?

A No. I don't know where NCI stands on this, whether there is-- they are still planning to go through this plan. But as far as the X-ray Department is concerned, we have not received a note indicating that we have entered such a Phase II study. But I know that they are discussing in their own institutes this topic, and whether they will materialize their plan or not is to be seen.

Q And it goes on to say, "These trials probably will begin during 1992." But obviously that hasn't happened, as far as you know?

A Exactly.

Q Okay. And the purpose of that, obviously, is to try to determine once and for all, in a controlled environment, whether or not the antineoplastons are or are not effective on those tumors?

A Well, to see the-- determine whether-- the percentage of response effectively, and try to dig out the issue further so we can find the full truth. And if somebody produces some data, another institute has to reproduce them in order to gain more weight. And this is something that

it's wise to go through this. And I'm sorry they have not done this yet.

Q Now, on Page 2 of the document, if you will turn to the next page with me, the first full paragraph on there, this says, "The NCI's decision to study an agent in clinical trials does not indicate that the agent will be useful in the treatment of cancer, only that it merits evaluation." And certainly, that's a true statement, isn't it?

A Yeah.

Q It also indicates that you have, or the NCI has over 160 different, I presume, investigational agents in clinical trials; is that correct?

A I don't know if they have 160 or less. But if they counted them and they found them to be the correct number--

Q I'm sure.

A --okay.

Q But it goes on to say they "...recommends that antineoplastons, like any other experimental cancer treatment, be administered only in the context of appropriately conducted and independently monitored clinical trials." Is that what we talk about as a scientific method here to try to determine whether or not the substance will produce, by independent tests, measurable or objective results?

A As I said a moment ago, I think it is wise; could it produce any good results somebody else has claimed, reproduce. Then the results are meaningful and can be applied to larger populations. So this has to be done.

Q And it goes on to say that "Cancer patients are encouraged to remain in the care of trained oncologists, and NCI encourages patients interested in antineoplastons or other investigational therapy to ask their physician to determine whether they are eligible for peer-reviewed clinical trials supported by NCI or other institutions."

Now, this is something that you are, I guess in the broadest sense a part of; is that correct?

A Well, this is National Cancer Institute. I am a private contract worker providing consultations for them. We are a separate entity. They are federal employees, I'm not. But we are working under the same roof.

Q All right, and that's really the point here. I mean, what we are about is Dr. Burzynski claims and has presented to you seven patients, five of which showed a, what I would term a positive response, using as best you could determine, his antineoplastons. What does that really prove? What does that really mean?

A It means that there may be something in these medications that we have not been aware of previously, and we may have bypassed these medications as being noneffective in the

past, but we are-- we have a new candle lighting up and we need to look at it more carefully.

Q And as they say, this merits evaluation. Not that it is necessarily going to be useful in the treatment of cancer, but that it merits further investigation; is that right?

A It does, yes.

Q And it merits that investigation in a properly conducted, I believe the term is peer-reviewed clinical trials. Is that not what we are trying to get to?

A They are going to do that, and this is how they are set up.

Q Shouldn't that be what has been done in this case? I mean, shouldn't that have occurred in this--

A How the NCI would know-- It should have been done already you mean? What do you--

Q Not necessarily by the NCI. Let me rephrase my question.

I think we can stipulate, and there has been testimony and evidence to the fact that Dr. Burzynski has been doing this with various different antineoplaston compounds since about 1977. It would seem to me, as a lay person, that somewhere along the-- somewhere along that line since 1977 this kind of clinical trial in that controlled peer review clinical experiment, that that should have taken place.

A Well, it could not have taken place because NCI people

never, to my knowledge, paid a site visit to Dr. Burzynski's facility to know exactly-- to get a hint of some kind of effectiveness.

Q I still didn't make my question very clear. And I understand NCI couldn't do it if they didn't know about it. I'll ask you more specifically. Dr. Burzynski has known about this since 1977. Wouldn't you think that somewhere between 1977 and 1993 that he would have tried to do this?

MR. JAFFE: Objection--

THE WITNESS: He may have already done--

JUDGE CORBITT: Just a minute.

MR. JAFFE: Objection. Speculative, beyond the knowledge of this witness.

JUDGE CORBITT: Any response to the objection that it is speculative?

MR. HELMCAMP: I think it's within the nature of what the witness has been able to testify to. I don't think it calls for any unnecessary conclusion.

JUDGE CORBITT: I'll sustain the objection. Go ahead, ask another one.

BY MR. HELMCAMP:

Q Other than the report that you have provided as Exhibit

27, have you submitted any other official reports as part of this team that went down to Houston?

A Not myself, I wasn't in it. I have not been involved in any other report.

MR. HELMCAMP: I'll pass the witness.

JUDGE CORBITT: Any Redirect?

MR. JAFFE: No, Your Honor.

JUDGE CORBITT: I don't have any questions for you, Doctor. You may step down.

Any reason to keep the witness?

MR. JAFFE: No, Your Honor.

MR. HELMCAMP: No, sir.

JUDGE CORBITT: You are excused, sir. Thank you very much.

THE WITNESS: Thank you.

JUDGE CORBITT: You may continue.

MR. JAFFE: Thank you, Your Honor. Call Dr. Burzynski.

JUDGE CORBITT: Dr. Burzynski, have a seat up here, please. Will you raise your right hand, please, sir?

STANISLAW R. BURZYNSKI, M.D., Ph.D.,

called as a witness by the Respondent, after having been first